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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/212,367	12/15/1998	DAVID BAUNOCH	98.714	8537

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/212,367	BAUNOCH ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 23-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 23-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claims 6 and 23-32 is withdrawn in view of the newly recited rejections based on the reference(s) of Kinney et al.(US 4,001,460) and/or Muller et al.(EP 508 568) follow.

Claim Objections

2. Claim 6 is objected to because of the following informalities: The language "the processor controlling the fluid flow selector in order to automatically and sequentially connect the processing chamber with the liquid containing container of clearant" (See lines 29-30 of claim 6) is redundant and no necessary. Note the last lines of the claim now recite the processor control of the fluid flow selector. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al.(US 4,001,460).

The reference of Kinney et al. discloses a tissue processing apparatus that includes a processing chamber (12); a fluid flow selector (39) for selecting the fluid flow to the processing chamber; at least one container of clearant agent (7, 8, 9); at least one container of contaminated dehydrant agent (10); at least one container of dehydrant agent (2-6); at least one container of an aqueous fluid (1); a plurality of first conduits (38); and a control device (100).

With respect to claim 23, the reference discloses a cleaning operation that includes sequentially contacting the chamber with the container of clearant (9), the container of contaminated dehydrant (10) and an aqueous fluid or container (1) (See column 9, lines 13-56). However, the instant claim includes the additional steps of contacting the chamber with the container of dehydrant agent after the container of contaminated dehydrant agent and before the container of aqueous fluid.

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to flush the chamber with "clean" dehydrant agent after contact with the contaminated dehydrant for the known and expected result of further cleaning or rinsing the chamber with an agent that is free of contaminants thereby further removing and/or limiting the contaminants that may be present prior to processing an additional tissue sample in the system.

Whether the cleaning discussed above is performed manually or automatically would have been clearly within the purview of one having ordinary skill in the art while providing the required sequence of steps as suggested above. Note, providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. (See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)).

Note while the rejection as set forth above does not involve reprocessing of a tissue specimen, the specific reagents employed and sequence of regents meets the instant claim limitations.

With respect to claim 24, the container of clearant (9) is considered to be a contaminated clearant agent since it is used to clean the chamber after the infiltration steps. Furthermore, it would have been obvious to one of ordinary skill in the art to provide the additional step of rinsing the chamber with "clean" clearant after contact with the contaminated clearant for the known and expected result of further cleaning or rinsing the chamber with an agent that is free of contaminants thereby further removing and/or limiting the contaminants that may be present prior to processing an additional tissue sample in the system.

With respect to claims 25 and 26, the chamber is cleaned with the contaminated clearant to remove infiltrating medium and is considered to be a purge clearant.

With respect to claims 27 and 28, the chamber is cleaned with the contaminated dehydrant to remove infiltrating medium and is considered to be a purge dehydrant.

With respect to claim 29, the infiltrating medium is paraffin.

With respect to claim 30, the rotary valve (39) is capable of connecting any of the containers to the chamber in any sequence.

With respect to claim 31, the device of Kinney et al. discloses the use of a rotary valve and the operation of the rotary valve to perform the sequence as suggested above would meet this claim limitation.

With respect to claim 32, the processing cycle that contacts the chamber with containers 1-8 and paraffin container I meets the limitations of this claim.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al. (US 4,001,460) in view of Louder et al.(US 4,399,433) and Muller et al.(EP 0 508 568).

The reference of Kinney et al. has been discussed above.

With respect to claim 6, while the reference of Kinney et al. discloses that is it known in the art to employ a pressure control system to transport the processing liquids to and from the processing chamber and that it is known in the art to control the pressure within the processing chamber so as to improve the penetration of the tissue by the processing liquids (See column 7, lines 41-56), the reference is silent as to the use of a pressure sensor in fluid communication with the processing chamber.

With respect to the claimed pressure sensor, the reference of Louder et al. discloses that it is conventional in the art to provide a pressure sensor (24) in communication with a processing chamber (10) so as to monitor the pressure within the chamber and control the pressure control and flow in response to detected pressures in the processing chamber.

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the processing chamber of the reference of Kinney et al. with a pressure sensor for the known and expected result of providing an art recognized means for controlling and monitoring the pressure with respect to a tissue processing chamber. Monitoring the pressure within the chamber would be advantageous when providing the penetrating steps suggested by the reference of Kinney et al.

With respect to the claimed temperature sensor in fluid communication with the processing chamber, while the reference of Kinney et al. discloses a temperature regulation system (See column 7, lines 32-40), the reference fails to specifically disclose a temperature sensor in fluid communication with the processing chamber.

The reference of Muller et al. discloses that it is known in the art to provide a tissue processing chamber (112) with a temperature sensor for controlling the temperature of the processing chamber (See the processing chamber (112); temperature regulator (117) for regulating temperature in the processing chamber and including a heater and sensor in communication with the processing chamber (112) (See page 20, lines 15-25)).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a temperature regulation system that includes a temperature sensor in fluid communication with the processing chamber for the known and expected result of providing an art recognized means for providing the temperature regulation required of the reference of Kinney et al.

With respect to the recited purge dehydrant and purge clearant and related sequence of contacting the processing chamber, see the discussion of the rejection of claims 23-32 above.

The purge dehydrant is the same as the contaminated dehydrant and the purge clearant is the same as the contaminated clearant.

Response to Arguments

7. Applicant's arguments with respect to claims 6 and 23-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB